

REMARKS

The Final Office Action of March 18, 2004 has been received and considered. Applicant thanks Examiner Flood for granting a telephonic interview on July 7, 2004. The following amendments have been made pursuant to suggestions by the Examiner. In the Office Action, Claims 1 and 6-11, and 22-27 remain rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention. Claims 1 and 6-11 remain objected to under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has possession of the claimed invention. Claims 1 and 6-11, and 22-27 remain objected to under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Claims 8-11 remain objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 1, 8, 10, 22, 25 and 27 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Falconer et al., as evidenced by the teachings of Kartinos *et al.* and Mullins. Claims 1, 6, 8, 10, 22, 25 and 27 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of Kartinos *et al.* and Mullins. Claims 1, 8-11, 22, 25 and 27 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Falconer *et al.* in view of Love. Claims 1, 6, 8-11, 22 and 25 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Martyn *et al.* in view of Love.

Claims 1, 6-11 and 22-27 have been rejected. Claims 1, 8, 9 and 10 have been amended. Claim 7 has been cancelled. Claims 1, 6, 8-11 and 22-27 are now pending in the application. Reexamination and reconsideration of the claims are respectfully requested.

Rejection of Claims 1 and 6-11 Under 35 U.S.C. §112, First Paragraph Should be Withdrawn

Claims 1 and 6-11 remain rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has possession of the claimed invention. Claim 1 has been amended. Therefore, it is submitted that amended claims 1 and 6-11 overcome the outstanding rejection and do not raise any new issues. Withdrawal of the rejection is requested.

Claims 1 and 6-11, and 22-27 remain rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention. This rejection is respectfully traversed for the reasons described below.

Applicant submits that there is sufficient written description for “nonabsorbable biocompatible solution” to enable one skilled in the art to which it pertains to make and/or use the invention, as required by section 112, first paragraph (see M.P.E.P. 2163.02).

Applicant respectfully submits that functional features are implicit in the term “nonabsorbable biocompatible solution” as used to further define an agent that increases retrievable ductal fluid from a breast duct.

Thus, applicant submits that the term “nonabsorbable biocompatible solution” is clear and definite based on the plain meaning of the term, and respectfully requests reconsideration and withdrawal of the present rejection.

Rejection of Claims 1, 6-11 and 22-27 Under 35 U.S.C. §112, Second Paragraph Should be Withdrawn

Claims 1 and 6-11, and 22-27 remain objected to under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

Applicant respectfully traverse the foregoing rejection on the grounds that the term “nonabsorbable biocompatible solution” is clear and definite, in view of the teachings in Applicants’ specification and the knowledge available in the art at the time of the invention.

Applicant respectfully submits that functional features are implicit in the term “nonabsorbable biocompatible solution” as used to further define an agent that increases retrievable ductal fluid from a breast duct.

In view of the foregoing, it is Applicants’ position that the term “nonabsorbable biocompatible solution” as used in the pending claims is clear and definite and respectfully requests reconsideration and withdrawal of the present rejection.

Claim 7 remains rejected under 35 U.S.C. § 112, second paragraph as being vague and indefinite. Although Applicant believes that the limitations of Claim 7 clearly define a subset of the members recited in the Markush group of Claim 1, in order to expedite prosecution, Applicant has canceled Claim 7, without prejudice or disclaimer, thereby obviating the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

#### Claim Objections

Claims 8-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 8 has been amended, thereby obviating the rejection. Applicant respectfully requests reconsideration and withdrawal of the present objection.

#### Rejection of Claims 1, 8, 10, 22, 25 and 27 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1, 8, 10, 22, 25 and 27 remain rejected to under 35 U.S.C. § 102(b) as being anticipated by Falconer *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins.

Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Falconer *et al.* describes an *in vivo* experiment in rabbits to measure the effect of prolactin and ouabain on mammary alveolar tissue. Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Dextran Blue 2000) as an agent to increase the secretion of ductal fluid into a breast duct. In fact, as evidenced

on page 182, Column 2, lines 13-15, Falconer *et al.* explicitly states that Dextran Blue 2000 is used to "...locate the injected glands at the time of removal". Similarly, Falconer *et al.* does not teach a method for administering intraductally to a patient an agent that increases the secretion of ductal fluid into a breast duct. As evidenced on page 185, Column 1, lines 4-8, Falconer *et al.* explicitly states that "From these results we conclude that *in vitro* and *in vivo* prolactin has significant influence upon Na<sup>+</sup> and K<sup>+</sup> content (and therefore Na<sup>+</sup>/K<sup>+</sup> ratio) of mammary alveolar tissue". Alveolar tissue is comprised of glandular tissue and secreting cells that surround the ductal system (see page 182, Column 2, lines 29-33). Therefore, Falconer *et al.* does not disclose that prolactin and ouabain increases water content in breast ducts, but instead, discloses an increase in water content of the surrounding alveolar tissue. There is no teaching or suggestion in Falconer *et al.* of an agent that increases the secretion of ductal fluid into a breast duct.

Accordingly, the rejection Falconer *et al.* should not be applied to newly amended Claim 1 nor dependent Claims 8, 10, 22, 25 and 27 for all of the reasons stated above. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 6, 8, 10, 22, 25 and 27 remain rejected to under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins.

As mentioned previously, Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Martyn *et al.* describes an *in vivo* experiment in rabbits to measure the effect of prolactin and progesterone on lipogenic-enzyme activity and glycerolipid synthesis. Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Blue Dextran 2,000,000) as an agent to increase the secretion of ductal fluid into a breast duct. In fact, as evidenced on page 326, Column 1, lines 28-41, as well as Table 4 on page 326, Blue Dextran mixed with Phosphate-buffered saline had no effect on fatty acid synthesis. Similarly, there is no teaching or

suggestion that any agent described in Martyn *et al.*, including Blue Dextran, would increase secretion into a breast duct.

Accordingly, the rejection Martyn *et al.*, should not be applied to newly amended Claim 1 nor dependent Claims 8, 10, 22, 25 and 27 for all of the reasons stated above. Reconsideration and withdrawal of the rejection is respectfully requested.

The Rejections Under 35 U.S.C. §103(a) Should be Withdrawn

Claims 1, 8-11, 22, 25 and 27 remain rejected under 35 U.S.C. 103 as being unpatentable over Falconer *et al.*, *supra* in view of U.S. Patent No. 6,221,622 to Love. Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Applicants submit that Falconer *et al.* neither anticipates the amended claims nor are they made obvious by Love. Because Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. Love does not disclose an agent to increase the secretion of fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Love does not recite any agent that increases the amount of secreted fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Combining Falconer *et al.* with the Love cannot make up for the deficiencies of Falconer *et al.* with respect to the claimed invention. Neither Falconer *et al.* nor Love teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, nor can they be combined to anticipate all the elements of the claimed invention. *Prima facie* obviousness has not been established under such conditions.

Accordingly, the rejection should not be applied to newly amended Claim 1 nor dependent Claims 8-11, 22, 25 and 27 for all of the reasons stated above. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 8-11, 22, 25 and 27 remain rejected under 35 U.S.C. 103 as being unpatentable over Martyn *et al. supra* in view of U.S. Patent No. 6,221,622 to Love. Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. Love does not disclose an agent to increase the secretion of fluid into a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Love does not recite any agent that increases the amount of secreted fluid into a breast duct, it cannot anticipate all the elements of the claimed invention. Combining Martyn *et al.* with the Love cannot make up for the deficiencies of Martyn *et al.* with respect to the claimed invention. Neither Martyn *et al.* nor Love teach a method of using a nonabsorbable biocompatible solution as an agent to increase the secretion of fluid into a breast duct, nor can they be combined to anticipate all the elements of the claimed invention. *Prima facie* obviousness has not been established under such conditions.

Accordingly, the rejection should not be applied to newly amended Claim 1 nor dependent Claims 8-11, 22, 25 and 27 for all of the reasons stated above. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims for Obviousness-Type Double Patenting

Claims 1, 6-11 and 22-27 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 157-165 of co-pending Application No. 09/907,581. Applicant will continue to defer consideration of filing a terminal disclaimer until determination of allowable subject matter by the Patent Office.

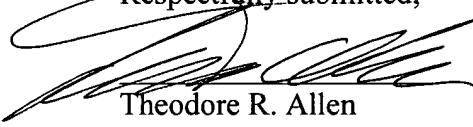
CONCLUSION

In light of the amendments and arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

A petition for one month extension of time is enclosed herewith. Any additional fee required (including fees for net addition of claims) is hereby authorized to debit or credit (respectively) Deposit Account No. 502855 referencing attorney docket number 12.023011. The Examiner may call the Assignee's attorney at (978) 929-3490 to further advance prosecution of this case to issuance.

Customer No.  
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Respectfully submitted,



Theodore R. Allen  
Registration No. 41,578  
Cytac Corporation  
85 Swanson Road,  
Boxborough, MA 01719  
Tel: 978-929-3490